

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

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SMITHKLINE BEECHAM CORP., and :  
BEECHAM GROUP, P.L.C., :  
Plaintiffs, :  
v. : Civil Action No.  
EON LABS MANUFACTURING INC., : 98-1611  
Defendant. :  
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**EON LABS MANUFACTURING, INC.'S  
ANSWER, COUNTER CLAIM AND JURY DEMAND**

Eon Labs Manufacturing, Inc. ("Eon"), through its attorneys, Cohen, Pontani, Lieberman & Pavane, answers the Complaint as follows:

1. Eon denies having sufficient knowledge and information on which to form a belief as to the allegations of ¶¶ 1 and 2 of the Complaint.
2. Eon admits the allegations of ¶ 3 of the Complaint.
3. Eon admits the allegations of ¶ 4 of the Complaint.
4. Eon admits that SmithKline Beecham is the owner of an NDA approved by the U.S. F.D.A. on December 24, 1991 for nabumetone which has anti-inflammatory activity in humans and that SmithKline Beecham sells nabumetone under the trademark Relafen® but is without knowledge or information sufficient to form a belief as to the remainder of the allegations of ¶ 5 of the Complaint.

5. Eon denies that U.S. Patent No. 4,420,639 ("the '639 Patent") was duly and legally issued but otherwise admits the allegations of ¶ 6 of the Complaint.

6. Eon lacks sufficient knowledge or information on which to form a belief as to the date on which SmithKline received Notice of Eon's certification but otherwise admits the allegations of ¶ 7 of the Complaint.

7. Eon admits filing an ANDA to engage in the commercial manufacture, use or sale of nabumetone before the expiration of the '639 Patent and a certification under 21 U.S.C. §355(j)(2)(A)(vii)(IV) with respect to the '639 Patent, but otherwise denies the allegations of ¶ 8 of the Complaint.

8. Eon denies the allegations of ¶ 9 of the Complaint.

9. Eon admits prior awareness of the existence of the '639 Patent but otherwise denies the allegations of ¶ 10 of the Complaint.

10. Eon denies the allegations of ¶¶ 11 to 14 of the Complaint.

11. Eon denies that either plaintiff is entitled to any relief requested in ¶ 15 of the Complaint.

#### FIRST AFFIRMATIVE DEFENSE

12. U.S. Patent No. 4,420,639 ("the '639 Patent) is invalid because of its failure to comply with one or more criteria of U.S. Patent Laws, 35 U.S.C. §101 *et. seq.* and more particularly its failure to comply with the requirements of 35 U.S.C. §102, §103 and §112.

## SECOND AFFIRMATIVE DEFENSE

13. The '639 patent is unenforceable by reason of Beecham's breach of the duty of candor to the U.S. Patent and Trademark Office by one or more of those under a duty of candor by way of one or more misrepresentations, and/or misstatements, and/or omissions made with knowledge of the falsity or misleading nature of such misrepresentations, and/or misstatements, and/or omissions and made with the intent to mislead so as to induce the Examiner to allow one or more of the applications which led to the '639 Patent. In particular, Beecham, and/or one under a duty of candor to the PTO, intentionally misrepresented to the Examiner that the oil produced by the procedure in The Chatterjea Paper could not be nabumetone when in fact Beecham knew the oil did contain nabumetone, that the acetate starting material referred to by Chatterjea was not produced by the Jones procedure set forth in The Jones Article when in fact Beecham knew or should have known that Jones did indeed produce the acetate starting material. Further, Beecham knew, based on its own testing that Prasad had produced the proper precursor nitrile and further knew that if the proper nitrile had not been produced, there would not have been a reaction product of the nitrile but failed to so advise the Examiner.

## COUNTERCLAIM

Without waiver of any defense, Eon, by way of its attorneys for its counterclaim, alleges as follows:

1. This is a counterclaim by Eon Labs Manufacturing Inc. against SmithKline Beecham Corporation ("SmithKline Beecham") and Beecham Group p.l.c. ("Beecham Group") for a declaratory judgment that U.S. Patent No. 4,420,639 (the "'639 Patent") is invalid and/or unenforceable.

2. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. §1 *et. seq.* This Court has subject matter jurisdiction based upon 28 U.S.C. §§1331 and 1338(a) and Rule 13 of the Federal Rules of Civil Procedure. Venue is proper in this district pursuant to 28 U.S.C. §1391.

3. Upon information and belief, counterclaim defendant SmithKline Beecham Corp. is a Pennsylvania Corporation, with its principal place of business at One Franklin Plaza, Philadelphia, Pennsylvania 19101.

4. Upon information and belief, counterclaim defendant Beecham Group p.l.c. is a United Kingdom Corporation, with its principal place of business in Brentford, United Kingdom.

5. Eon is a Delaware Corporation, with its principal place of business at 225-15 N. Conduit Avenue, Laurelton, New York 11413.

6. Plaintiffs have alleged that Beecham Group p.l.c. is the owner of the '639 Patent, which claims nabumetone, and that SmithKline Beecham Corp. sells nabumetone under license from Beecham Group under the trademark Relafen®. Both SmithKline Beecham Corp.

license from Beecham Group under the trademark Relafen®. Both SmithKline Beecham Corp. and Beecham Group p.l.c. have instituted legal action against Eon accusing it of infringement of the '639 Patent.

7. The '639 Patent is invalid under one or more sections of 35 U.S.C. §101 *et. seq.* More particularly, *infra.*, the '639 Patent is invalid under 35 U.S.C. §102, §103 and §112.

8. The '639 Patent is unenforceable by reason of Beecham's breach of the duty of candor to the U.S. Patent and Trademark Office by one or more of those under a duty of candor by way of one or more misrepresentations, and/or misstatements, and/or omissions made with knowledge of the falsity or misleading nature of such misrepresentations, and/or misstatements, and/or omissions and made with the intent to mislead so as to induce the Examiner to allow one or more of the applications which led to the '639 Patent. In particular, Beecham and/or one under a duty of candor to the PTO, intentionally misrepresented to the Examiner that the oil produced by the procedure in The Chatterjea Paper could not be nabumetone when in fact Plaintiff knew the oil did contain nabumetone, that the acetate starting material referred to by Chatterjea was not produced by the Jones procedure set forth in The Jones Article when in fact Beecham knew or should have known that Jones did indeed produce the acetate starting material. Further, Beecham knew, based on its own testing that Prasad produced the proper precursor nitrile and further knew that if the proper nitrile had not been produced, there would not have been a reaction product of the nitrile but failed to so advise the Examiner.

WHEREBY, Eon requests

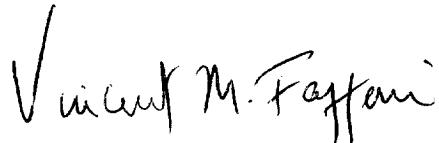
- a) Judgment be entered that the '639 Patent is invalid;
- b) Judgment be entered that the '639 Patent is unenforceable
- c) Judgment be entered for costs and reasonable attorney fees be awarded to defendant;
- d) Judgment be entered for such other and further relief as the Court may deem proper.

**JURY DEMAND**

Eon requests a trial by jury on all issues triable to a jury.

Dated: March 13, 1998

Respectfully submitted,



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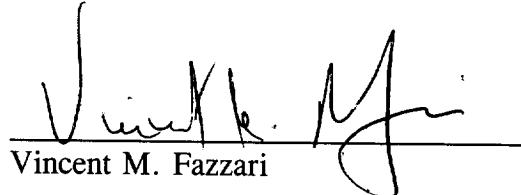
Attorneys for Defendant

**CERTIFICATE OF SERVICE**

I certify that a true and correct copy of the foregoing Eon Labs Manufacturing, Inc.'s Answer, Counter Claim and Jury Demand was served by First Class Mail, postage prepaid, on counsel for Plaintiffs as follows:

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Dated: March 13, 1998

  
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